1.0 Purpose:

To define a set of guidelines for the reprocessing of single-use, or disposable medical devices (SUD)

Note: This policy does not address the reprocessing of devices that are marketed or labeled as reusable or multi-use devices.

2.0 Definitions:

Single-Use or Disposable Device: A device that is marketed or labeled for single patient use or single procedure use. It is **not** marketed or labeled with the intent of reusing the device on another patient. The labeling identifies the device as single-use, or disposable and does not include instructions for reprocessing.

Note: Some SUDs are marketed and labeled as non-sterile and include appropriate pre-use sterilization or processing instructions to make the device patient ready. This is not considered "reprocessing".

Open but Unused: An "Open but Unused" product is a SUD whose sterility has been breached or whose sterile package was opened but the device has not been used on a patient. This also includes a device whose packaging has expired as identified by the label on the package.

Reuse: The repeated use or multiple use of any medical device on the same patient or different patients, with applicable reprocessing (cleaning, functionality verification, and/or disinfecting /sterilization) between uses.

Reprocessing: Includes all operations performed to assure that a previously used SUD is clean, sterile and will function as intended by the original equipment manufacturer (OEM). The process includes, but is not limited to, disinfection, cleaning, functional verification, packaging and possible sterilization.

Resterilization: The repeated application of a terminal process designed to remove or destroy all viable forms of microbial life, including bacterial spores, to an acceptable sterility level.

3.0 Policy:

3.1 Apollo Hospital, Secunderabad is committed to reprocess SUD's in a manner so as to ensure patient safety and stringent quality controls.

3.2 SUD's that may be reprocessed are those listed in Appendix I. SUD's not listed cannot be reprocessed and shall be discarded after single use.

3.3 Authority:

Authority for the program is vested with the Infection Control Committee.

4.0 Procedure:

4.1 Sorting:

An initial sort of each SUD shall take place to eliminate obvious rejects or unapproved products.

4.2 Cleaning:

SUD shall be washed immediately after use in running water with pressure so that it cleaned thoroughly to eliminate any blood or other body fluids. Hollow instruments shall be flushed with enzymatic detergents and cleaned with a brush. The SUD shall then be placed in Cidezyme solution to dissolve all protein residues. The SUD shall then be thoroughly rinsed with water and left to dry.

4.3 Testing:

Verifying that devices perform as intended shall be an integral component of the reprocessing cycle. This can involve injection of water through the catheters, or other device-specific functional indicators.

4.4 Packaging:

All devices shall be packaged, sealed and labeled in Hospital approved pouches for ETO purposes. Prior to packing, a dot with a permanent marker

shall be placed on the device, indicating the number of times it has been reused.

4.5 Sterilization:

Sterilization shall be performed in state-of-the-art ETO gas sterilizer. Every load shall contain chemical and biological indicators that shall be sent to the Microbiology laboratory for testing once a week. All load shall pass PCD before sending it out of CSSD.

4.6 Labeling requirements:

All reprocessed SUD shall be labeled with number of times the device has been used and date of reprocessing. In addition, a non-repeatable number shall be allocated to the device in order to facilitate recall of the device.

4.7 SUD Recall:

Any SUD found to be unsafe due to repetitive incidents or due to a report by Microbiology Department or from manufacturers, shall be immediately recalled and disposed off as per hospital policy for waste management.

4.8 Disposal:

All devices that have been reused the number of times as per policy, shall be mutilated and disposed off as per hospital policy for waste management.